Complete Summary

GUIDELINE TITLE

Public Health Service Task Force recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States.

BIBLIOGRAPHIC SOURCE(S)

Perinatal HIV Guidelines Working Group. Public Health Service Task Force recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States. Rockville (MD): Public Health Service Task Force; 2005 Feb 24. 55 p. [243 references]

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Human immunodeficiency virus (HIV) infection
- Acquired immunodeficiency syndrome (AIDS)

GUIDELINE CATEGORY

Management
Prevention
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To update the December 17, 2004 guidelines developed by the Public Health Service for the use of antiretroviral drugs to reduce the risk for perinatal human immunodeficiency virus type 1 (HIV-1) transmission
- To provide health care providers with information for discussion with HIV-1-infected pregnant women to enable such women to make an informed decision regarding the use of antiretroviral drugs during pregnancy and use of elective cesarean delivery to reduce perinatal HIV-1 transmission

TARGET POPULATION

Human immunodeficiency virus type 1 (HIV-1)-infected pregnant women and their infants in the United States

INTERVENTIONS AND PRACTICES CONSIDERED

Antiretroviral Therapy in Human Immunodeficiency Virus-1 (HIV-1)-Infected Pregnant Women Who Have Not Received Prior Antiretroviral Therapy*

1. Zidovudine (ZDV) chemoprophylaxis three-part regimen to reduce the risk for perinatal transmission of HIV: (1) oral ZDV initiated at 14 to 34 weeks' gestation and continued throughout pregnancy, (2) intravenous ZDV during labor, and (3) oral administration of ZDV to the newborn (or intravenous ZDV if oral intake is not tolerated) for 6 weeks after delivery

2. Combination of above ZDV chemoprophylaxis with additional antiretroviral drugs for intrapartum/neonatal antiretroviral prophylaxis to reduce perinatal transmission of HIV-1

Antiretroviral Therapy in HIV-1-Infected Women Receiving Antiretroviral Therapy During the Current Pregnancy

1. Continuation of current antiretroviral therapy, when pregnancy is identified after the first trimester, with addition of ZDV to the regimen
2. Counseling of women of the benefits and risks of continued antiretroviral therapy if pregnancy is recognized in first trimester
3. Stopping and reintroducing antiviral drugs simultaneously to avoid drug resistance, if therapy is stopped during first trimester

Antiretroviral Therapy in HIV-1-Infected Women in Labor Who Have Had No Prior Therapy

1. Intrapartum intravenous ZDV followed by 6 weeks of ZDV for the newborn
2. Oral ZDV and lamivudine (3TC) during labor, followed by one week of oral ZDV-3TC for the newborn
3. A single-dose nevirapine* at onset on labor, followed by single dose nevirapine* for the newborn at age 48 hours
4. Two-dose nevirapine* regimen combined with intrapartum intravenous ZDV and 6-week ZDV for the newborn
5. Postpartum assessment (e.g., CD4+ count and HIV-1 RNA copy number) to determine potential antiretroviral therapy

Antiretroviral Therapy for Infants Born to Mothers Who Have Received No Therapy During Pregnancy or Intrapartum

1. Initiation of 6 weeks of ZDV therapy as soon as possible after delivery
2. Combination of ZDV with other antiretroviral drugs
3. Early diagnostic testing for infant to determine if HIV-1 infection treatment should be initiated
4. Postpartum assessment (e.g., CD4+ count and HIV-1 RNA copy number) to determine potential antiretroviral therapy

General Management Practices in Pregnant HIV-1-Infected Women, Including Labor and Delivery Management, to Reduce Perinatal HIV-1 Transmission

1. Monitoring of mother for HIV-1 status (e.g., clinical assessment, CD4+ count, and HIV-1 RNA copy number) and drug side effects
2. Monitoring of infant for HIV-1 status (e.g., virologic diagnostic tests) and drug side effects (e.g., hemoglobin measurement)
3. Preconception counseling and care for HIV-1-infected women of childbearing age
4. General counseling regarding known and unknown short- and long-term benefits and risks of antiretroviral therapy for infected women and their infants
5. Resistance testing in pregnancy

6. General counseling regarding the benefit of scheduled cesarean delivery in reducing the risk of vertical transmission of HIV-1, as well as the risks to the mother associated with cesarean delivery
7. Scheduled cesarean section at 38 weeks gestation combined with intravenous ZDV initiated 3 hours prior to surgery to reduce intrapartum transmission of HIV-1
8. Postpartum follow-up of infants and mothers

Antiretroviral Therapy Considered

- Nucleoside and nucleotide analogue reverse transcriptase inhibitors, such as zidovudine (Retrovir, AZT, ZDV); zalcitabine (HIVID, ddC); didanosine (Videx, ddI); stavudine (Zerit, d4T); lamivudine (Epivir, 3TC); abacavir (Ziagen, ABC); tenofovir disoproxil fumarate (DF) (Viread)

  Note from the National Guideline Clearinghouse™: The U.S. Food and Drug Administration's (FDA) MedWatch Safety program distributed information from the manufacturer (Gilead Sciences, Inc) of tenofovir disoproxil fumarate (Viread®) about a high rate of early virologic failure and emergence of nucleoside reverse transcriptase inhibitor (NRTI) resistance associated mutations with the use of the drug in a once-daily triple NRTI regimen along with didanosine enteric coated beadlets (Videx EC, Bristol-Myers Squibb), and lamivudine (Epivir, GlaxoSmithKline). Based on these results, Tenofovir DF in combination with didanosine and lamivudine is not recommended when considering a new treatment regimen for therapy-naïve or experienced patients with HIV infection. Patients currently on this regimen should be considered for treatment modification. For more information, visit the FDA Web site.

- Non-nucleoside reverse transcriptase inhibitors, such as nevirapine* (Viramune), delavirdine (Rescriptor), and efavirenz (Sustiva)
- Protease inhibitors, such as indinavir (Crixivan), ritonavir (Norvir), saquinavir (Fortavase), nelfinavir (Viracept), amprenavir (Agenerase), and lopinavir/ritonavir (Kaletra)
- Fusion inhibitors, such as enfuvirtide (Fuzeon,T-20)

*Note from the National Guideline Clearinghouse: On January 19, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine. The Indications and Usage section now recommends against starting nevirapine treatment in women with CD4+cell counts greater than 250 cells/mm^3 unless benefits clearly outweigh risks. This recommendation is based on a higher observed risk of serious liver toxicity in patients with higher CD4 cell counts prior to initiation of therapy. See the FDA Web site for more information.

MAJOR OUTCOMES CONSIDERED

- Perinatal transmission of human immunodeficiency virus type 1 (HIV-1) from mother to newborn
- Adverse and teratogenic effects of drug treatment on the fetus
- Adverse effects of drug treatment on HIV-1-infected women

- Maternal viral load (HIV-1 ribonucleic acid [RNA] levels)
- Complications of cesarean delivery

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review
Review of Published Meta-Analyses

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Combination Antiretroviral Therapy and Pregnancy Outcome

Data are conflicting as to whether receipt of combination antiretroviral therapy during pregnancy is associated with adverse pregnancy outcomes such as preterm delivery. Until more information is known, it is recommended that human immunodeficiency virus-1 (HIV-1)-infected pregnant women who are receiving combination therapy for treatment of their HIV-1 infection should continue their provider-recommended regimen. They should receive careful, regular monitoring for pregnancy complications and for potential toxicities.

Nevirapine* and Hepatic/Rash Toxicity

Although deaths due to hepatic failure have been reported in HIV-infected pregnant women receiving nevirapine* as part of a combination antiretroviral regimen, it is unknown if pregnancy increases the risk of hepatotoxicity in women receiving nevirapine* or other antiretroviral drugs. Women initiating nevirapine* with CD4+ counts >250 cells/mm^3, including pregnant women receiving antiretroviral drugs solely for prevention of transmission, have an increased risk of developing symptomatic, often rash-associated, nevirapine*-related hepatotoxicity, which can be severe, life-threatening, and in some cases fatal. Nevirapine* should therefore be used as a component of a combination regimen in this setting only if the benefit clearly outweighs the risk. Regardless of maternal CD4+ cell count, if nevirapine* is used, health care providers should be aware of this potential complication and should conduct frequent and careful monitoring of clinical symptoms and hepatic transaminases (i.e., ALT and AST), particularly during the first 18 weeks of therapy. Transaminase levels should be checked in all women who develop a rash while receiving nevirapine*. Patients who develop suggestive clinical symptoms accompanied by elevation in serum transaminase levels (ALT and/or AST), or who have asymptomatic but severe transaminase elevations, should stop nevirapine* and not receive nevirapine* therapy in the future.

*See the Note regarding the U.S. Food and Drug Administration (FDA) public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine at the end of the "Major Recommendations" field.

Preconceptional Counseling and Care for HIV-1-Infected Women of Childbearing Age

The following components of preconceptional counseling are recommended for HIV-1-infected women:

- Selection of effective and appropriate contraceptive methods to reduce the likelihood of unintended pregnancy
- Education and counseling about perinatal transmission risks, strategies to reduce those risks, and potential effects of HIV-1 or treatment on pregnancy course and outcomes
- Initiation or modification of antiretroviral therapy:
    - Avoid agents with potential reproductive toxicity for the developing fetus (e.g., efavirenz, hydroxyurea). See the companion document titled "Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy" available from the AIDSinfo Web site.
    - Choose agents effective in reducing the risk of perinatal HIV-1 transmission.
    - Attain a stable, maximally suppressed maternal viral load.
    - Evaluate and control for therapy-associated side effects that may adversely impact maternal-fetal health outcomes (e.g., hyperglycemia, anemia, hepatic toxicity).
- Evaluation and appropriate prophylaxis for opportunistic infections and administration of medical immunizations (e.g., influenza, pneumococcal, or hepatitis B vaccines) as indicated
- Optimization of maternal nutritional status
- Institution of the standard measures for preconception evaluation and management (e.g., assessment of reproductive and familial genetic history, screening for infectious diseases/sexually transmitted diseases, and initiation of folic acid supplementation)
- Screening for maternal psychological and substance abuse disorders.
- Planning for perinatal consultation if desired or indicated

HIV-1-infected women of childbearing potential receive primary health care services in various clinical settings (e.g., family planning, family medicine, internal medicine, obstetrics/gynecology). It is imperative that primary health care providers consider the fundamental principles of preconception counseling an integral component of comprehensive primary health care for improving maternal/child health outcomes.

Recommendations for Antiretroviral Chemoprophylaxis to Reduce Perinatal HIV-1 Transmission

Recommendations for the use of antiretroviral chemoprophylaxis to reduce the risk for perinatal transmission are based on situations that may be commonly encountered in clinical practice (see Table 4 titled "Clinical Scenarios and Recommendations for the Use of Antiretroviral Drugs to Reduce Perinatal Human

Immunodeficiency Virus Type 1 [HIV-1] Transmission" in the original guideline document). These recommendations are only guidelines and flexibility should be exercised according to the patient's individual circumstances.

The antenatal dosing regimen in the Pediatric AIDS Clinical Trials Group (PACTG) 076 (100 mg administered orally five times daily) (see the table titled "Pediatric AIDS Clinical Trials Group [PACTG] 076 Zidovudine [ZDV] Regimen" below) was selected on the basis of standard zidovudine (ZDV) dosage for adults at the time of the study.

However, recent data have indicated that administration of ZDV three times daily will maintain intracellular ZDV triphosphate at levels comparable with those observed with more frequent dosing. Comparable clinical response also has been observed in some clinical trials among persons receiving ZDV twice daily. Thus, the current standard ZDV dosing regimen for adults is 200 mg three times daily or 300 mg twice daily. Because the mechanism by which zidovudine reduces perinatal transmission is not known, these dosing regimens may not have equivalent efficacy to that observed in PACTG 076. However, a regimen of two- or three-times daily is expected to increase maternal adherence to the regimen.

The recommended ZDV dosage for infants was derived from pharmacokinetic studies performed among full-term infants. Results of a pharmacokinetic study of ZDV dosing in infants <35 weeks gestation at birth (PACTG 331) indicated that the appropriate dose of ZDV for preterm infants is 1.5 mg/kg/dose intravenously, or 2.0 mg/kg/dose orally, every 12 hours, advancing to every 8 hours at 2 weeks of age if ≥30 weeks gestation at birth or at 4 weeks of age if <30 weeks gestation at birth.

Table. Pediatric AIDS Clinical Trials Group (PACTG) 076 Zidovudine (ZDV) Regimen

Time of Zidovudine (ZDV) Administration	Regimen
Antepartum	Oral administration of 100 mg ZDV five times daily*, initiated at 14 to 34 weeks' gestation and continued throughout the pregnancy *Note: Oral ZDV administered as 200 mg three times daily or 300 mg twice daily is currently used in general clinical practice and is an acceptable alternative regimen to 100 mg orally five times daily.
Intrapartum	During labor, intravenous administration of ZDV in a one-hour initial dose of 2 mg/kg body weight, followed by a continuous infusion of 1 mg/kg body weight/hour until delivery.

Time of Zidovudine (ZDV) Administration	Regimen
Postpartum	Oral administration of ZDV to the newborn (ZDV syrup at 2 mg/kg body weight/dose every 6 hours) for the first 6 weeks of life, beginning at 8 to 12 hours after birth. (Note: intravenous dosage for full-term infants who cannot tolerate oral intake is 1.5 mg/kg body weight intravenously every 6 hours. ZDV dosing for infants <35 weeks gestation at birth is 1.5 mg/kg/dose intravenously, or 2.0 mg/kg/dose orally, every 12 hours, advancing to every 8 hours at 2 weeks of age if >30 weeks gestation at birth or at 4 weeks of age if <30 weeks gestation at birth)

Antiretroviral Clinical Scenarios**

Scenario No. 1: HIV-1-Infected Pregnant Women Who Have Not Received Prior Antiretroviral Therapy

- Pregnant women with HIV-1 infection must receive standard clinical, immunologic, and virologic evaluation. Recommendations for initiation and choice of antiretroviral therapy should be based on the same parameters used for persons who are not pregnant, although the known and unknown risks and benefits of such therapy during pregnancy must be considered and discussed.
- The three-part zidovudine (ZDV) chemoprophylaxis regimen, initiated after the first trimester, is recommended for all pregnant women with HIV-1 infection regardless of antenatal HIV-1 RNA copy number to reduce the risk for perinatal transmission.
- The combination of ZDV chemoprophylaxis with additional antiretroviral drugs for treatment of HIV-1 infection is recommended for infected women whose clinical, immunologic, or virologic status requires treatment or whose HIV-1 RNA >1,000 copies/mL regardless of clinical or immunologic status, and can be considered for women with HIV-1 RNA
- Women who are in the first trimester of pregnancy may consider delaying initiation of therapy until after 10 to 12 weeks' gestation.

Scenario No. 2: HIV-1-Infected Women Receiving Antiretroviral Therapy During the Current Pregnancy

- HIV-1-infected women receiving antiretroviral therapy whose pregnancy is identified after the first trimester should continue therapy. ZDV should be a component of the antenatal antiretroviral treatment regimen after the first trimester whenever possible, although this may not always be feasible.
- Women receiving antiretroviral therapy in whom pregnancy is recognized during the first trimester should be counseled regarding the benefits and potential risks of antiretroviral administration during this period, and continuation of therapy should be considered. If therapy is discontinued

during the first trimester, all drugs should be stopped and reintroduced simultaneously to avoid the development of drug resistance.
- Regardless of the antepartum antiretroviral regimen, ZDV administration is recommended during the intrapartum period and for the newborn.

Scenario No. 3: HIV-1-Infected Women in Labor Who Have Had No Prior Therapy

- Several effective regimens are available (see Table 5 titled "Comparison of Intrapartum/Postpartum Regimens for HIV-1-Infected Women in Labor Who Have Had No Prior Antiretroviral Therapy [Scenario #3]" in the original guideline document). These include: (1) intrapartum intravenous ZDV followed by six weeks of ZDV for the newborn; (2) oral ZDV and lamivudine (3TC) during labor, followed by one week of oral ZDV-3TC for the newborn; (3) a single dose of nevirapine* at the onset of labor followed by a single dose of nevirapine* for the newborn at age 48 hours; and (4) the two-dose nevirapine* regimen combined with intrapartum intravenous ZDV and six week ZDV for the newborn.
- In the immediate postpartum period, the woman should have appropriate assessments (e.g., CD4+ count and HIV-1 RNA copy number) to determine whether antiretroviral therapy is recommended for her own health.

*See the Note regarding the U.S. Food and Drug Administration (FDA) public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine at the end of the "Major Recommendations" field.

Scenario No. 4: Infants Born to Mothers Who Have Received No Antiretroviral Therapy During Pregnancy or Intrapartum

- The 6-week neonatal component of the ZDV chemoprophylactic regimen should be discussed with the mother and offered for the newborn.
- ZDV should be initiated as soon as possible after delivery, preferably within 6 to 12 hours of birth.
- Some clinicians may use ZDV in combination with other antiretroviral drugs, particularly if the mother is known or suspected to have ZDV-resistant virus. However, the efficacy of this approach for prevention of transmission has not been proven in clinical trials, and appropriate dosing regimens for neonates are incompletely defined for many drugs.
- In the immediate postpartum period, the woman should undergo appropriate assessments (e.g., CD4+ count and HIV-1 RNA copy number) to determine if antiretroviral therapy is required for her own health. The infant should undergo early diagnostic testing so that if he or she is HIV-1 infected, treatment can be initiated as soon as possible.

**Note: Discussion of treatment options should be noncoercive, and the final decision regarding use of antiretroviral drugs is the responsibility of the woman. A decision to not accept treatment with ZDV or other drugs should not result in punitive action or denial of care. Use of ZDV should not be denied to a woman who wishes to minimize exposure of the fetus to other antiretroviral drugs and who therefore, after counseling, chooses to receive only ZDV during pregnancy to reduce the risk for perinatal transmission.

Antiretroviral Drug Resistance and Resistance Testing in Pregnancy

Recommendations Related to Antiretroviral Drug Resistance and Drug Resistance Testing for Pregnant Women with HIV-1 Infection:

- All pregnant HIV-1-infected women should be offered highly active antiretroviral therapy to maximally suppress viral replication, reduce the risk of perinatal transmission, and minimize the risk of development of resistant virus.
- For women for whom combination antiretroviral therapy would be considered optional (HIV-1 RNA <1,000 copies/mL) and who wish to restrict their exposure to antiretroviral drugs during pregnancy, monotherapy with the three-part ZDV prophylaxis regimen (or in selected circumstances, dual nucleosides) should be offered. In these circumstances, the development of resistance should be minimized by limited viral replication (assuming HIV-1 RNA levels remain low) and the time-limited exposure to ZDV. Monotherapy with ZDV does not suppress HIV-1 replication to undetectable levels in most cases. Theoretically, such therapy might select for ZDV-resistant viral variants, potentially limiting future treatment options. These considerations should be discussed with the pregnant woman.
- Recommendations for resistance testing in HIV-1-infected pregnant women are the same as for non-pregnant patients: acute HIV-1 infection, virologic failure, sub-optimal viral suppression after initiation of antiretroviral therapy, or high likelihood of exposure to resistant virus based on community prevalence or source characteristics.
- Women who have a history of presumed or documented ZDV resistance and are on antiretroviral regimens that do not include ZDV for their own health, should still receive intravenous ZDV intrapartum and oral ZDV for their infants according to the PACTG 076 protocol whenever possible. A key mechanism by which ZDV reduces perinatal transmission is likely through pre- and post-exposure prophylaxis of the infant, which may be less dependent on drug sensitivity than is reduction of viral replication. However, these women are not good candidates for ZDV alone.
- Optimal antiretroviral prophylaxis of the infant born to a woman with HIV-1 known to be resistant to ZDV or other agents should be determined in consultation with pediatric infectious disease specialists, taking into account resistance patterns, available drug formulations, and infant pharmacokinetic data, when available.
- If women receiving combination therapy require temporary discontinuation for any reason during pregnancy, all drugs should be stopped and reintroduced simultaneously to reduce the potential for emergence of resistance.
- Optimal adherence to antiretroviral medications is a key part of the strategy to reduce the development of resistance.
- Because the prevalence of drug-resistant virus is an evolving phenomenon, surveillance is needed to monitor the prevalence of drug-resistant virus in pregnant women over time and the risk of transmission of resistant viral strains.

The optimal prophylactic regimen for newborns of women with ZDV resistance is unknown. Therefore, antiretroviral prophylaxis of the infant born to a woman with known or suspected ZDV-resistant HIV-1 should be determined in consultation with pediatric infectious disease specialists.

Perinatal HIV-1 Transmission and Mode of Delivery

Recommendations

Considerations related to counseling of the HIV-1-infected pregnant woman regarding risks for vertical transmission of HIV-1 to the fetus/neonate and to the obstetric care of such women include the following:

- Efforts to maximize the health of the pregnant woman, including the provision of highly active combination antiretroviral therapy, can be expected to correlate with both reduction in viral load and low rates of vertical transmission. At a minimum for the reduction of perinatal HIV-1 transmission, ZDV prophylaxis according to the PACTG 076 regimen is recommended unless the woman is intolerant of ZDV.
- Plasma HIV-1 RNA levels should be monitored during pregnancy according to the guidelines for management of HIV-1-infected adults. The most recently determined viral load value should be used when counseling a woman regarding mode of delivery.
- Perinatal HIV-1 transmission is reduced by scheduled cesarean delivery among women with unknown HIV-1 RNA levels who are not receiving antiretroviral therapy or are receiving only ZDV for prophylaxis of perinatal transmission. Plasma HIV-1 RNA levels were not available in these studies to assess the potential benefit among women with low plasma HIV-1 RNA levels.
- Women with HIV-1 RNA levels >1,000 copies/mL should be counseled regarding the potential benefit of scheduled cesarean delivery in reducing the risk of vertical transmission. The benefit among women on highly active antiretroviral regiments (HAART) is unproven.
- Data are insufficient to evaluate the potential benefit of cesarean delivery for neonates of antiretroviral-treated women with plasma HIV-1 RNA levels below 1,000 copies/mL. Given the low rate of transmission among this group, it is unlikely that scheduled cesarean delivery would confer additional benefit in reduction of transmission.
- Management of women originally scheduled for cesarean delivery who present with ruptured membranes or in labor must be individualized based on duration of rupture, progress of labor, plasma HIV-1 RNA level, current antiretroviral therapy, and other clinical factors. It is not clear that cesarean delivery after rupture or onset of labor provides benefit in reducing transmission.
- Women should be informed of the risks associated with cesarean delivery; these risks to the woman should be balanced with potential benefits expected for the neonate.
- Women should be counseled regarding the limitations of the current data. The woman's autonomy to make an informed decision regarding route of delivery should be respected and honored.

Mode of Delivery Clinical Scenarios

The following recommendations are based on various hypothetical situations that may be encountered in clinical practice (see Table 8 titled "Clinical Scenarios and Recommendations Regarding Mode of Delivery to Reduce Perinatal Human Immunodeficiency Virus Type I [HIV-1] Transmission" in the original guideline

document). These recommendations are only guidelines, and flexibility should be exercised according to the patient's individual circumstances.

Scenario A: HIV-1-infected women presenting in late pregnancy (after approximately 36 weeks of gestation), known to be HIV-1 infected but not receiving antiretroviral therapy, and whose results for HIV-1 RNA level and lymphocyte subsets are pending but unlikely to be available before delivery.

- Therapy options should be discussed in detail. Antiretroviral therapy, including at least the PACTG 076 ZDV regimen, should be initiated. In counseling, the woman should be informed that scheduled cesarean section is likely to reduce the risk of transmission to her infant. She should also be informed of the increased risks to her of cesarean delivery, including increased rates of postoperative infection, anesthesia risks, and other surgical risks.
- If cesarean delivery is chosen, the procedure should be scheduled at 38 weeks of gestation, based on the best available clinical information. When scheduled cesarean section is performed, the woman should receive continuous intravenous ZDV infusion beginning 3 hours before surgery, and her infant should receive 6 weeks of ZDV therapy after birth. Options for continuing or initiating combination antiretroviral therapy after delivery should be discussed with the woman as soon as her viral load and lymphocyte subset results are available.

Scenario B: HIV-1-infected women who began prenatal care early in the third trimester, are receiving highly active combination antiretroviral therapy, and have an initial virologic response, but have HIV-1 RNA levels that remain substantially over 1,000 copies/mL at 36 weeks of gestation.

- The current combination antiretroviral regimen should be continued because the HIV-1 RNA level is declining appropriately. The woman should be informed that although her HIV-1 RNA level is responding to the antiretroviral therapy, it is unlikely that it will reach <1,000 copies/mL before delivery. Therefore, scheduled cesarean delivery may provide additional benefit in preventing intrapartum transmission of HIV-1. She should also be informed of the increased risks to her of cesarean delivery, including increased rates of postoperative infection, anesthesia risks, and surgical risks.
- If she chooses scheduled cesarean section, it should be performed at 38 weeks' gestation, and intravenous ZDV should be started at least 3 hours before surgery. Other antiretroviral medications should be continued on schedule as much as possible before and after surgery. The infant should receive oral ZDV for 6 weeks after birth. The importance of adhering to therapy after delivery, for her own health, should be emphasized.

Scenario C: HIV-1-infected women receiving highly active combination antiretroviral therapy who have an undetectable HIV-1 RNA level at 36 weeks of gestation.

- The woman should be informed that her risk of perinatal transmission of HIV-1 with a persistently undetectable HIV-1 RNA level is low, probably 2% or less, even with vaginal delivery. Current information suggests that performing

a scheduled cesarean delivery will not lower her risk further. Cesarean delivery has an increased risk of complications for the woman compared with vaginal delivery, and these risks must be balanced against the uncertain benefit of cesarean delivery in this case.

Scenario D: HIV-1-infected women who have elected scheduled cesarean delivery but present in early labor or shortly after rupture of membranes.

- Intravenous ZDV should be started immediately since the woman is in labor or has ruptured membranes.
- If cervical dilatation is minimal and a long period of labor is anticipated, the clinician may administer the loading dose of intravenous ZDV and proceed as expeditiously as possible with cesarean delivery to minimize the duration of membrane rupture and avoid vaginal delivery. Alternatively, the clinician might begin pitocin augmentation to enhance contractions and potentially expedite delivery.
- If labor is progressing rapidly, the woman should be allowed to deliver vaginally.
- If the woman is allowed to labor, scalp electrodes and other invasive monitoring and operative delivery should be avoided if possible. Other antiretrovirals besides ZDV should be continued orally during labor. The infant should be treated with 6 weeks of ZDV therapy after birth.

Recommendations for the Monitoring of Women and Their Infants

Pregnant Woman and Fetus

HIV-1-infected pregnant women should be monitored according to the same standards for monitoring HIV-1-infected persons who are not pregnant. This monitoring should include measurement of CD4+ T-lymphocyte counts and HIV-1 RNA levels approximately every trimester (i.e., every 3 to 4 months) to determine (a) the need for antiretroviral therapy of maternal HIV-1 disease, (b) whether such therapy should be altered, and (c) whether prophylaxis against Pneumocystis carinii pneumonia should be initiated.

Changes in absolute CD4+ count during pregnancy may reflect the physiologic changes of pregnancy on hemodynamic parameters and blood volume as opposed to a long-term influence of pregnancy on CD4+ count; CD4+ percentage is likely more stable and might be a more accurate reflection of immune status during pregnancy. Long-range plans should be developed with the woman regarding continuity of medical care and antiretroviral therapy for her own health after the birth of her infant.

Monitoring for potential complications of the administration of antiretrovirals during pregnancy should be based on what is known about the side effects of the drugs the woman is receiving. For example, routine hematologic and liver enzyme monitoring is recommended for women receiving ZDV. Because combination antiretroviral regimens have been used less extensively during pregnancy, more intensive monitoring may be warranted for women receiving drugs other than or in addition to ZDV. For example, women receiving protease inhibitors should be monitored for development of hyperglycemia. Women, particularly those with CD4+ counts >250 cells/mm^3, have an increased risk of developing symptomatic,

rash-associated, nevirapine-associated hepatotoxicity; thus, pregnant women receiving nevirapine* should have frequent and careful monitoring of transaminase levels, particularly during the first 18 weeks of treatment.

*See the Note regarding the U.S. Food and Drug Administration (FDA) public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine at the end of the "Major Recommendations" field.

Antepartum fetal monitoring for women who receive only ZDV chemoprophylaxis should be performed as clinically indicated, because data do not indicate that ZDV use in pregnancy is associated with increased risk for fetal complications. Less is known about the effect of combination antiretroviral therapy on the fetus during pregnancy. Thus, more intensive fetal monitoring should be considered for mothers receiving such therapy, including assessment of fetal anatomy with a level II ultrasound and continued assessment of fetal growth and well being during the third trimester.

Neonate

A complete blood count and differential should be performed on the newborn as a baseline evaluation before administration of ZDV. Anemia has been the primary complication of the 6-week ZDV regimen in the neonate; thus, repeat measurement of hemoglobin is required at a minimum after the completion of the 6-week ZDV regimen. If abnormal, repeat measurement should be performed at 12 weeks of age, by which time any ZDV-related hematologic toxicity should be resolved. Infants who have anemia at birth or who are born prematurely warrant more intensive monitoring.

Data are limited concerning potential toxicities in infants whose mothers have received combination antiretroviral therapy. More intensive monitoring of hematologic and serum chemistry measurements during the first few weeks of life is advised in these infants. However, it should be noted that the clinical relevance of lactate levels in the neonatal period to assess potential for mitochondrial toxicity has not been adequately evaluated.

To prevent Pneumocystis carinii pneumonia, all infants born to women with HIV-1 infection should begin prophylaxis at 6 weeks of age, after completion of the ZDV prophylaxis regimen. Monitoring and diagnostic evaluation of HIV-1 exposed infants should follow current standards of care. Data do not indicate any delay in HIV-1 diagnosis in infants who have received the ZDV regimen. However, the effect of combination antiretroviral therapy in the mother or newborn on the sensitivity of infant virologic diagnostic testing is unknown. Infants with negative virologic test results during the first 6 weeks of life should have diagnostic evaluation repeated after completion of the neonatal antiretroviral prophylaxis regimen.

Postpartum Follow-Up of Women

Comprehensive care and support services are important for women with HIV-1 infection and their families. Components of comprehensive care include the following medical and supportive care services:

- Primary, obstetric, pediatric and HIV-1 specialty care
- Family planning services
- Mental health services
- Substance-abuse treatment
- Coordination of care through case management for the woman, her children, and other family members

Support services may include case management, child care, respite care, assistance with basic life needs (e.g., housing, food, and transportation), and legal and advocacy services. This care should begin before pregnancy and should be continued throughout pregnancy and postpartum.

Maternal medical services during the postpartum period must be coordinated between obstetric care providers and HIV-1 specialists. Continuity of antiretroviral treatment when such treatment is required for the woman's HIV-1 infection is especially critical and must be ensured. Concerns have been raised about adherence to antiretroviral regimens during the postpartum period. Women should be counseled about the fact that the physical changes of the postpartum period, as well as the stresses and demands of caring for a new baby, can make adherence more difficult and additional support may be needed to maintain good adherence to their therapeutic antiretroviral regimen during this period. The health care provider should be vigilant for signs of depression, which may require assessment and treatment and which may interfere with adherence. Poor adherence has been shown to be associated with virologic failure, development of resistance, and decreased long-term effectiveness of antiretroviral therapy. Efforts to maintain good adherence during the postpartum period might prolong the effectiveness of therapy. See the "Adherence" section in the guideline document titled "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents," available at the AIDSinfo Web site (see the related National Guideline Clearinghouse [NGC] summary Guidelines for the Use of Antiretroviral Agents in HIV-infected Adults and Adolescents).

All women should receive comprehensive health care services that continue after pregnancy for their own medical care and for assistance with family planning and contraception. In addition, this is a good time to review immunization status and update vaccines, assess the need for prophylaxis against opportunistic infections, and re-emphasize safer sex practices.

Data from PACTG 076 and 288 do not indicate adverse effects through 4 years postpartum among women who received ZDV during pregnancy. Women who have received only ZDV chemoprophylaxis during pregnancy should receive appropriate evaluation to determine the need for antiretroviral therapy during the postpartum period.

Long-Term Follow-Up of Infants

Data remain insufficient to address the effect that exposure to ZDV or other antiretroviral agents in utero might have on long-term risk for neoplasia or organ system toxicities in children. Data from follow-up of PACTG 076 infants through age 6 years do not indicate any differences in immunologic, neurologic, and growth parameters between infants who were exposed to the ZDV regimen and those who received placebo, and no malignancies have been seen. There are

conflicting data regarding whether mitochondrial dysfunction is associated with perinatal antiretroviral exposure. Mitochondrial dysfunction should be considered in uninfected children with perinatal antiretroviral exposure who present with severe clinical findings of unknown etiology, particularly neurologic findings.

Continued evaluation of early and late effects of in utero antiretroviral exposure is ongoing through several mechanisms, including a long-term follow-up study in the PACTG 219C, natural history studies, and HIV/AIDS surveillance conducted by state health departments and the Centers for Disease Control and Prevention (CDC). Because most of the available follow-up data relate to in utero exposure to antenatal ZDV alone and most pregnant women with HIV-1 infection currently receive combination therapy, it is critical that studies to evaluate potential adverse effects of in utero drug exposure continue to be supported.

Innovative methods are needed to provide follow-up of infants with in utero exposure to antiretroviral drugs. Information regarding such exposure should be part of the ongoing permanent medical record of the child, particularly for uninfected children. Children with in utero antiretroviral exposure who develop significant organ system abnormalities of unknown etiology, particularly of the nervous system or heart, should be evaluated for potential mitochondrial dysfunction. Follow-up of children with antiretroviral exposure should continue into adulthood because of the theoretical concerns regarding potential for carcinogenicity of the nucleoside analog antiretroviral drugs. Long-term follow-up should include yearly physical examinations of all children exposed to antiretroviral drugs and, for adolescent females, gynecologic evaluation with Pap smears.

HIV-1 surveillance databases from states that require HIV-1 reporting provide an opportunity to collect population-based information concerning in utero antiretroviral exposure. To the extent permitted by federal law and regulations, data from these confidential registries can be used to compare with information from birth defect and cancer registries to identify potential adverse outcomes.

*Note from the National Guideline Clearinghouse: On January 19, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine. The Indications and Usage section now recommends against starting nevirapine treatment in women with CD4+cell counts greater than 250 cells/mm^3 unless benefits clearly outweigh risks. This recommendation is based on a higher observed risk of serious liver toxicity in patients with higher CD4 cell counts prior to initiation of therapy. See the FDA Web site for more information.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations for reduction of risk of perinatal-human immunodeficiency virus (HIV) transmission are primarily based on review of randomized controlled clinical trials, epidemiologic studies, prospective cohort trials, observational studies, case studies, pharmacokinetic studies and meta-analyses of clinical studies.

The recommendations for the benefit of cesarean delivery in reducing the risk of perinatal-HIV transmission are based on an international randomized trial of elective cesarean section versus vaginal delivery. These recommendations are also based on a meta-analysis of 15 prospective cohort studies, including more than 7,800 mother-child pairs that evaluated the rate of perinatal-HIV transmission in women undergoing elective cesarean delivery versus non-elective cesarean or vaginal delivery.

Information regarding the safety of drugs in pregnancy is derived from animal toxicity data, anecdotal experience, registry data, and clinical trials. Data are limited for antiretroviral drugs, particularly when used in combination therapy.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Efforts to maximize the health of the pregnant woman, including the provision of highly active combination antiretroviral therapy, can be expected to correlate with both reduction in viral load and low rates of vertical transmission.
- The Pediatric AIDS Clinical Trials Group (PACTG) Protocol 076 revealed HIV-1 transmission rates for infants who received placebo were 22.6%, compared to 7.6% for those who received zidovudine (ZDV); this represents a 66% reduction in risk for transmission. This study also documented that ZDV chemoprophylaxis could reduce perinatal HIV-1 transmission by nearly 70%. Epidemiologic data have since confirmed the efficacy of ZDV for reduction of perinatal transmission and have extended this efficacy to children of women with advanced disease, low CD4+ T-lymphocyte counts, and prior ZDV therapy.
- Two clinical trials have suggested that the addition of the HIVNET 012 single-dose nevirapine* regimen to short-course ZDV may provide increased efficacy in reducing perinatal transmission.
- Studies done before routine viral load testing and combination antiretroviral therapy that became a routine part of clinical practice consistently show that cesarean delivery performed before the onset of labor and rupture of membranes (elective or scheduled cesarean) was associated with a significant decrease in perinatal HIV-1 transmission compared with other types of delivery, with reductions ranging from 55% to 80%.

*Note from the National Guideline Clearinghouse: On January 19, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine. The Indications and Usage section now recommends against starting nevirapine treatment in women with CD4+cell counts greater than 250 cells/mm3 unless

benefits clearly outweigh risks. This recommendation is based on a higher observed risk of serious liver toxicity in patients with higher CD4 cell counts prior to initiation of therapy. See the FDA Web site for more information.

POTENTIAL HARMS

- Maternal complications of antiretroviral therapy: Hematologic and hepatic toxicity is associated with zidovudine (ZDV); hyperglycemia is associated with protease inhibitors. In addition, nucleoside analogue drugs are known to induce mitochondrial dysfunction. These toxicities may be of particular concern for pregnant women and infants with in utero exposure to nucleoside analogue drugs. Clinical disorders linked to mitochondrial toxicity include neuropathy, myopathy, cardiomyopathy, pancreatitis, hepatic steatosis, and lactic acidosis. Among these disorders, symptomatic lactic acidosis and hepatic steatosis may have a female preponderance. (See the original guideline document for more details.)
- Nevirapine* toxicity: Increases in hepatic transaminase levels (ALT and AST) associated with rash or systemic symptoms may be observed during the first 18 weeks of treatment with nevirapine*. These toxicities have been reported in patients on chronic therapy, and have not been reported in women or infants receiving two-dose nevirapine* (the HIVNET 012 regimen) for prevention of perinatal transmission. Women initiating nevirapine* with CD4+ counts >250 cells/mm^3, including pregnant women receiving antiretroviral drugs solely for prevention of transmission, have an increased risk of developing symptomatic, often rash-associated, nevirapine*-related hepatotoxicity, which can be severe, life-threatening, and in some cases fatal. Nevirapine* should therefore be used as a component of a combination regimen in this setting only if the benefit clearly outweighs the risk. Regardless of maternal CD4+ cell count, if nevirapine* is used, health care providers should be aware of this potential complication and should conduct frequent and careful monitoring of clinical symptoms and hepatic transaminases (i.e., ALT and AST), particularly during the first 18 weeks of therapy. Transaminase levels should be checked in all women who develop a rash while receiving nevirapine*. Patients who develop suggestive clinical symptoms accompanied by elevation in serum transaminase levels (ALT and/or AST), or have asymptomatic but severe transaminase elevations, should stop nevirapine* and not receive nevirapine therapy in the future.
- Neonatal complications of ZDV therapy: Anemia has been the primary complication of the 6-week ZDV regimen in the neonate. Data remain insufficient to address the effect that exposure to zidovudine or other antiretroviral agents in utero might have on long-term risk for neoplasia or organ-system toxicities in children. Mitochondrial dysfunction should be considered in uninfected children with perinatal antiretroviral exposure who present with severe clinical findings of unknown etiology, particularly neurologic findings.
- Drug resistance: Use of antiretroviral therapy includes consideration of potential development of drug resistance in the woman and the infant, should the infant become infected despite prophylaxis, and the implications of such resistance for future treatment options and the efficacy of prophylaxis for future pregnancies.
- Maternal complications of cesarean delivery: Among women not infected with HIV-1, maternal morbidity and mortality are greater after cesarean than

after vaginal delivery. Complications, especially postpartum infections, are approximately five to seven times more common after cesarean delivery performed after labor or membrane rupture compared with vaginal delivery. Complications after scheduled cesarean delivery are more common than with vaginal delivery but less than with urgent cesarean delivery.

Data indicate that cesarean delivery is associated with a slightly greater risk of complications among HIV-1-infected women than observed among uninfected women, with the difference most notable among women with more advanced disease. Scheduled cesarean delivery for prevention of HIV-1 transmission poses a risk greater than that of vaginal delivery and less than that of urgent or emergent cesarean section. Complication rates in most studies were within the range reported in populations of HIV-1-uninfected women with similar risk factors and were not of sufficient frequency or severity to outweigh the potential benefit of reduced transmission among women at heightened risk of transmission. HIV-1-infected women should be counseled regarding the increased risks associated with cesarean delivery as well as the potential benefits based on their HIV-1 RNA levels and current antiretroviral therapy.

- Safety and toxicity of antiretroviral agents: Refer to Table 2 titled "Preclinical and Clinical Data Relevant to the Use of Antiretrovirals During Pregnancy" and Table 3 titled "Antiretroviral Drug Use in Pregnant HIV-Infected Women: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy" in the original guideline document, as well as the companion document titled "Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy," for important and detailed information regarding the safety and toxicity of individual antiretroviral drugs and combination antiretroviral therapy in pregnancy. Both the original guideline document and the companion document are available at the AIDSinfo Web site.

Subgroups Most Likely to be Harmed

Women with CD4+ counts >250 cells/mm^3 have an increased risk of developing symptomatic, rash-associated, nevirapine*-related hepatotoxicity.

*Note from the National Guideline Clearinghouse: On January 19, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine. The Indications and Usage section now recommends against starting nevirapine treatment in women with CD4+cell counts greater than 250 cells/mm^3 unless benefits clearly outweigh risks. This recommendation is based on a higher observed risk of serious liver toxicity in patients with higher CD4 cell counts prior to initiation of therapy. See the FDA Web site for more information.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Treatment with efavirenz should be avoided during the first trimester because significant congenital central nervous system abnormalities were seen in cynomolgus monkeys born to mothers who received efavirenz during pregnancy at drug exposures similar to those representing human exposure. Severe central nervous system defects have been reported in four infants after first trimester exposure to efavirenz-containing regimens (three infants with meningomyelocele and one with a Dandy-Walker malformation). Based on these data, efavirenz has been classified as U.S. Food and Drug Administration (FDA) Pregnancy Class D (positive evidence of human fetal risk) (see Table 2 titled "Preclinical and Clinical Data Relevant to the Use of Antiretrovirals During Pregnancy" in the original guideline document and the companion document titled "Safety and Toxicity of Individual Antiretroviral Drugs in Pregnancy").
- Hydroxyurea is a potent teratogen in a variety of animal species and should also be avoided during the first trimester.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Pregnancy should not preclude the use of optimal therapeutic regimens. However, recommendations regarding the choice of antiretroviral drugs for treatment of infected pregnant women are subject to unique considerations. These include possible changes in dosing requirements resulting from physiologic changes associated with pregnancy, potential effects of antiretroviral drugs on the pregnant woman, and the potential short- and long-term effects of the antiretroviral drug on the fetus and newborn, which may not be known for certain antiretroviral drugs. The decision to use any antiretroviral drug during pregnancy should be made by the woman after discussing with her health care provider the known and unknown benefits and risks to her and her fetus.
- These recommendations have been developed for use in the United States. Although perinatal HIV-1 transmission occurs worldwide, alternative strategies may be appropriate in other countries. Policies and practices in other countries regarding the use of antiretroviral drugs for reduction of perinatal HIV-1 transmission may differ from the recommendations in this report and will depend on local considerations, including availability and cost of antiretroviral drugs, access by pregnant women to facilities for safe intravenous infusions during labor, local recommendations regarding breastfeeding by HIV-1-infected women, and alternative interventions being evaluated in that area.
- More data are needed regarding the safety and pharmacokinetics of antiretroviral drugs in pregnant women and their neonates, particularly when used in combination regimens.
- Information included in these guidelines may not represent approval by the Food and Drug Administration (FDA) or approved labeling for the particular product or indications in question. Specifically, the terms "safe" and "effective" may not be synonymous with the FDA-defined legal standards for product approval.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

RELATED QUALITY TOOLS

- AIDSinfo's Drug Database for Palm PDAs
- AIDSinfo's HIV/AIDS Glossary for Palm PDAs
- AIDSInfo Drug Database
- HIV During Pregnancy, Labor and Delivery, and After Birth Fact Sheets
- A Pocket Guide to Adult HIV/AIDS Treatment: Companion to A Guide to Primary Care of People with HIV/AIDS August 2004 Edition

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Perinatal HIV Guidelines Working Group. Public Health Service Task Force recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States. Rockville (MD): Public Health Service Task Force; 2005 Feb 24. 55 p. [243 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 Jan 30 (revised 2005 Feb 24)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]
Department of Health and Human Services (U.S.) - Federal Government Agency [U.S.]
Public Health Service (U.S.) - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

GUIDELINE AVAILABILITY

Electronic copies of the updated guideline: Available from the AIDSinfo Web site.

The guideline is also available for Palm OS or Pocket PC download from the AIDSinfo Web site.

Print copies: Available from the Centers for Disease Control and Prevention, National Prevention Information Network (NPIN), P.O. Box 6003, Rockville, MD 20850. Telephone: (800) 458-5231, TTY (800)-243-7012 International number (301)-562-1098. Web site: http://www.cdcnpin.org. Requests for print copies can also be submitted via the AIDSinfo Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Department of Health and Human Services, Henry J. Kaiser Foundation. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. Bethesda (MD): Bethesda (MD): Department of Health and Human Services, Public Health Service (PHS), Centers for Disease Control and Prevention (CDC); 2004 Oct 29. 110 p. Available from the AIDSinfo Web site.
- Safety and toxicity of individual antiretroviral agents in pregnancy. 2001 Jan 24 (updated 2005 Feb 24). 23 p. Electronic copies: Available in Portable

Document Format (PDF) from the AIDSinfo Web site. Also available for Palm OS or Pocket PC download from the AIDSinfo Web site.

- Wortley PM, Lindegren ML, Fleming PL. Successful implementation of perinatal HIV prevention guidelines. A multistate surveillance evaluation. MMWR Recomm Rep. 2001 May 11;50(RR-6):17-28. Available from the AIDSinfo Web site.

Print copies: Available from the Centers for Disease Control and Prevention, National Prevention Information Network (NPIN), P.O. Box 6003, Rockville, MD 20850. Telephone: (800) 458-5231, TTY (800)-243-7012 International number (301)-562-1098. Web site: http://www.cdcnpin.org. Requests for print copies can also be submitted via the AIDSinfo Web site.

The following tools are also available:

- AIDSinfo's Drug Database for Palm PDAs. Electronic copies: Available from the AIDSinfo Web site.
- AIDSinfo's HIV/AIDS Glossary, 4th ed. Electronic copies: Available from the AIDSinfo Web site in HTML Format, Portable Document Format (PDF) English and Spanish, and for Palm PDAs.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 27, 1999. The original information was verified by the guideline developer on April 29, 1999. This summary was updated by ECRI on February 25, 2000, November 3, 2000, January 24, 2001, May 4, 2001, December 5, 2001, February 4, 2002, August 30, 2002, June 30, 2003, October 14, 2003, December 8, 2003, June 25, 2004, and December 21, 2004. This summary was updated on January 21, 2005, following the release of a public health advisory from the U.S. Food and Drug Administration regarding the use of nevirapine. This summary was updated most recently on March 2, 2005.

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